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(54) Non-adherent surgical instrument and method

(57) Method and means are disclosed for preventing tissue from adhering to surgical apparatus (e.g. a heated surgical scalpel) while operating at tissue temperatures (usually 100-500°C) at which haemostasis with minimal tissue damage occurs, and include interposing between the surgical apparatus 11 and the tissue 13 being heated thereby a non-adherent coating 12 which has specific parameters including thermal impedance, thickness and thermal drop thereacross. The coating 12 may be of fluorocarbon polymers, silicones, metallic fluorides or organic phosphates, or may be a sacrificial solid or liquid layer of waxes, greases, oils or other fluorinated polymers or silicones.

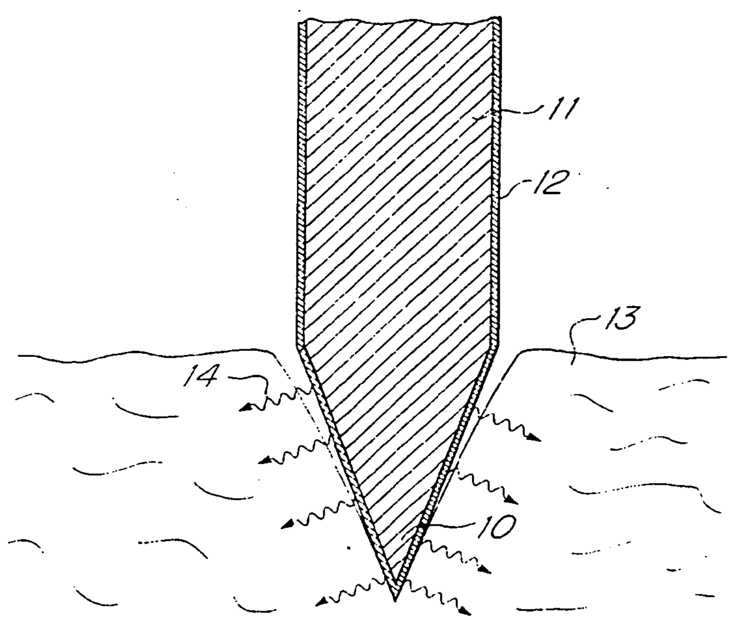

Fig 2

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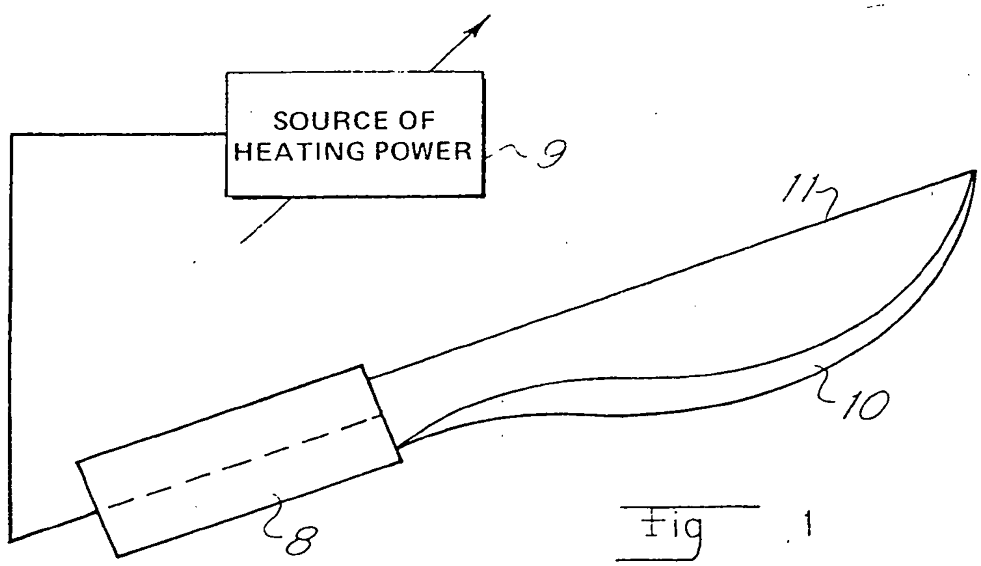

Fig 1

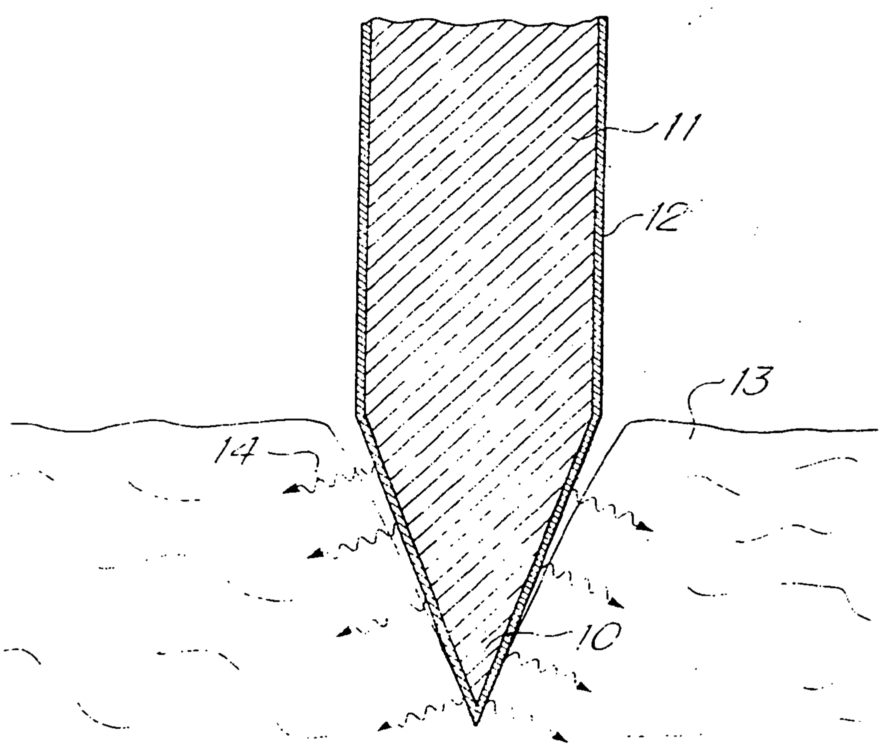

Fig 2

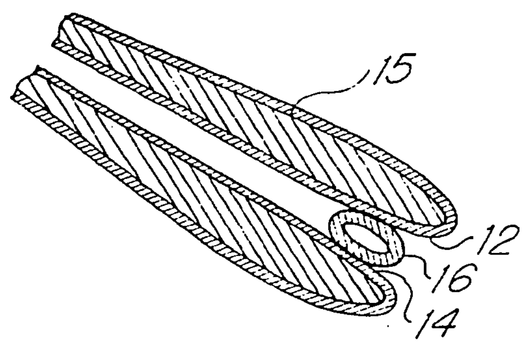

Fig 3

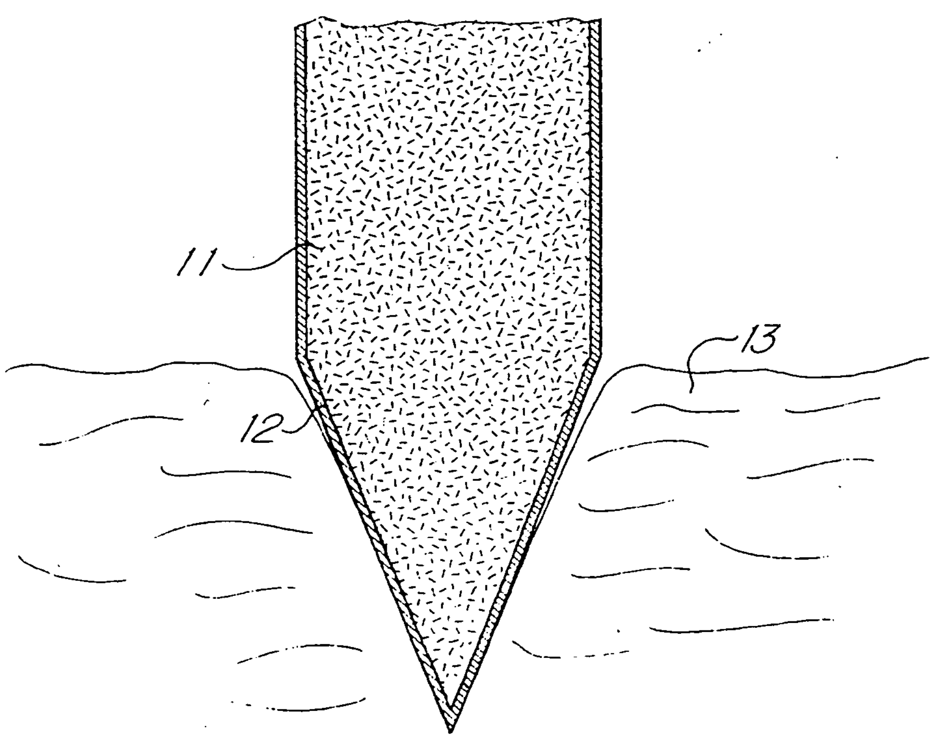

Fig 4

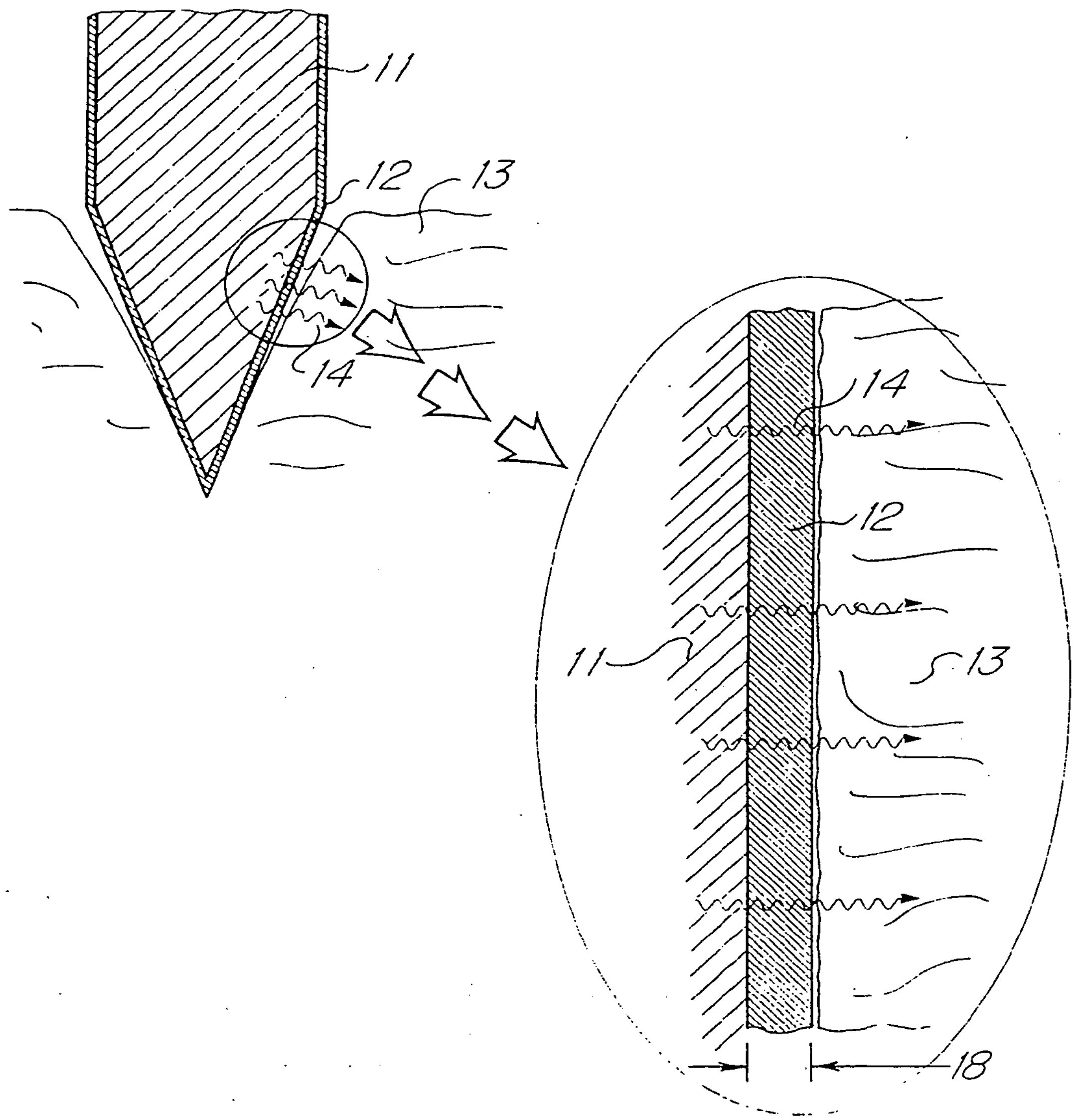

Fig 5

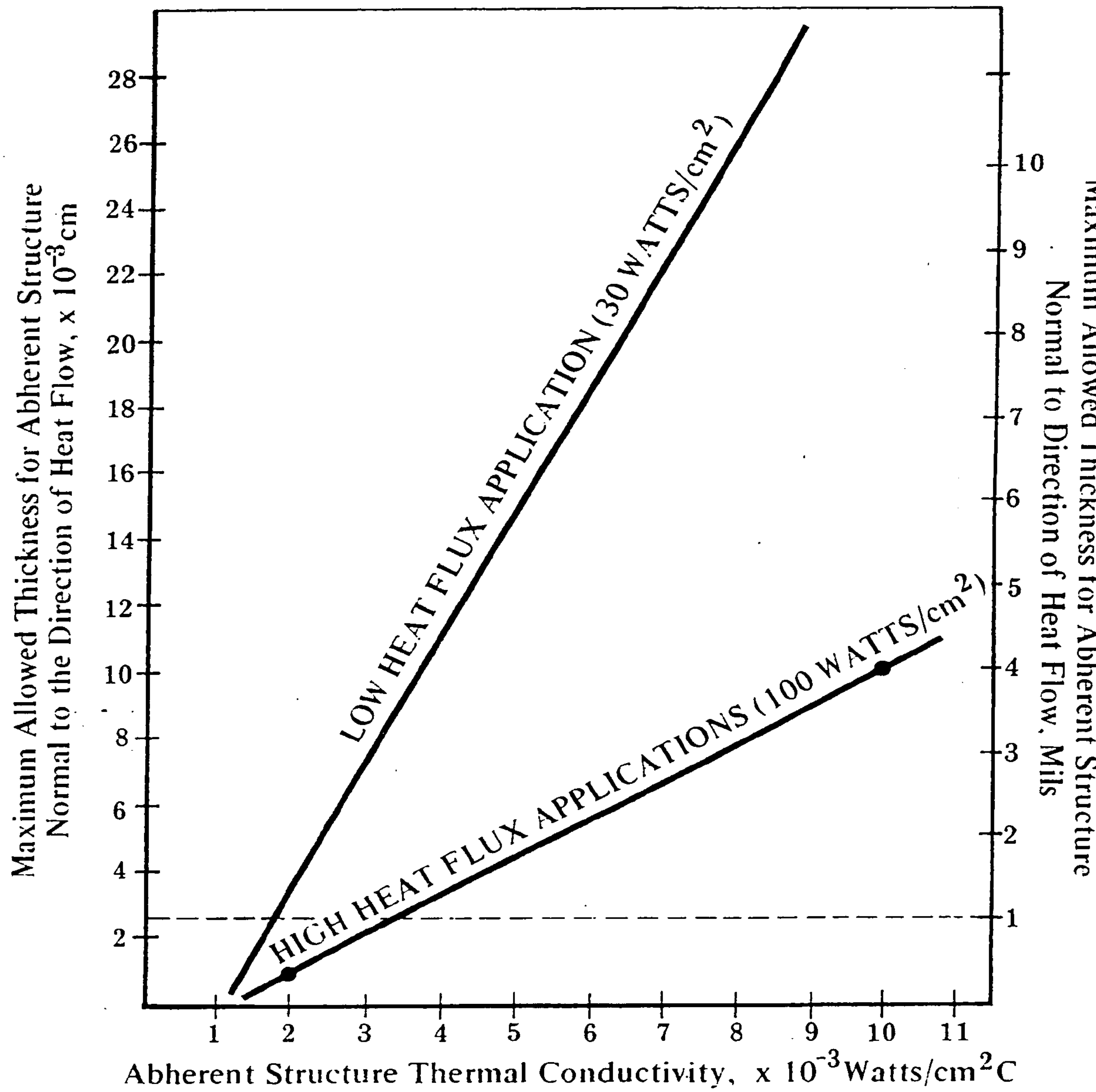
Maximum Allowed Thickness for Abherent Structure Normal to the Direction of Heat Flow, x 10^{-3}cm
28
26
24
22
20
18
16
14
12
10
8
6
4
2
LOW HEAT FLUX APPLICATION (30 WATTS/cm^2)
HIGH HEAT FLUX APPLICATIONS (100 WATTS/cm^2)
1 2 3 4 5 6 7 8 9 10 11
Abherent Structure Thermal Conductivity, x 10^{-3}Watts/cm^2C
10
9
8
7
6
5
4
3
2
1
Maximum Allowed Thickness for Abherent Structure Normal to Direction of Heat Flow, Mils

Fig 6

SPECIFICATION

Non-adherent surgical instrument and method

This invention is concerned with improvements in or relating to surgical instruments and with their method of use.

Surgical devices which heat tissue to provide hemostasis are described in the literature (see, for example, U S Patents RE 29,088, 4,091,813 and 4,185,632). The adherence of tissue to such surgical devices severely limits their usefulness because the resulting avulsion of tissue causes undesirable tissue damage and bleeding. Also, the adherence of tissue to such surgical devices limits the surgeon's control of the device, and the build-up of adherent tissue material causes apparent dullness of the device. Additionally, the build-up of adherent tissue material on heater-type surgical devices introduces a high thermal impedance between the heater and the tissue being cut that prevents heating of the tissues to the desired temperature. These problems of tissue adhering to the surgical device are especially severe for tissue temperatures within the range from about 100°C to about 500°C.

The applicant has discovered that the tissue temperature for the optimum condition of hemostasis with minimal tissue damage varies with the type of tissue being cut and may be as low as about 130°C (on the soft palate of the mouth) and as high as about 450°C to 500°C (on highly vascularized tissue), above which tissue adherence usually does not occur.

The present invention provides surgical apparatus for non-adherently contacting tissue to heat the tissue in contact therewith to an elevated temperature at which hemostasis with minimal tissue damage occurs, comprising: heating means operable at an elevated temperature for heating the tissue; and non-adherent coating means disposed to be intermediate the heating means and the tissue being heated thereby; said non-adherent coating means having a thermal impedance that is not substantially greater than

$$5\frac{°C \cdot cm^2}{watt}.$$

The present invention further provides surgical apparatus for non-adherently contacting tissue to heat the tissue in contact therewith to an elevated temperature at which hemostasis with minimal tissue damage occurs, comprising: heating means operable at an elevated temperature for heating the tissue; and non-adherent coating means disposed to be intermediate the heating means and the tissue being heated thereby; said non-adherent coating means having a thickness that is not substantially greater than .0025 cm.

The present invention further provides surgical apparatus for non-adherently contacting tissue to heat the tissue in contact therewith to an elevated temperature at which hemostasis with minimal tissue damage occurs, comprising: heating means operable at an elevated temperature for heating the tissue; and non-adherent coating means disposed to be intermediate the heating means and the tissue being heated thereby; said non-adherent coating means having a thermal drop thereacross while in contact with the tissue that is not substantially greater than 50°C for tissue temperatures within the range from about 100°C to about 500°C.

The present invention further provides surgical apparatus for non-adherently contacting tissue to heat the tissue in contact therewith to an elevated temperature at which hemostasis with minimal tissue damage occurs, comprising: heating means operable at an elevated temperature for heating the tissue; and non-adherent coating means disposed to be intermediate the heating means and the tissue being heated thereby; said non-adherent coating means having a maximum allowed thickness, t, in centimeters as given by the relationship:

$$t = \frac{50 \cdot k}{(Q/A)}$$

where k is thermal conductivity of the non-adherent coating in watts/cm°C, and Q/A is the heat flux in watts/cm².

In apparatus as set out forth in anyone of the last four immediately preceding paragraphs, the non-adherent coating means may include a composition selected from fluorocarbon polymers, silicone polymers, organic phosphates or metallic fluorides.

The present invention further provides a method of preventing adherence of surgical apparatus to tissue at an elevated temperature at which hemostasis with minimal tissue damage occurs, the method comprising the steps of: transferring heat to the tissue from the surgical apparatus; and interposing between the tissue and the surgical apparatus a non-adherent coating having a thickness which is not substantially greater than .0025 cm.

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$5\frac{°C. \cdot cm^2}{watt}$.

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In accordance with the present invention, the optimum conditions of hemostasis with minimal tissue damage can be attained by operating at tissue temperatures in the range from about 100°C to about 500°C and by introducing between the surgical device and the contacted tissue a non-adherent coating having specific thermal parameters.

More particularly, in surgical apparatus which operates at elevated temperatures for heating the tissue contacted thereby, the heat transfer from the apparatus to the tissue in regions of the apparatus in contact with tissues may be twenty times greater than the heat transfer from the apparatus to the air in regions of the apparatus that are not in contact with tissue. The heat transfer conditions vary widely as a function of the type of tissue being cut, the desired operating temperature, and the speed at which the device is moved through tissue.

To obtain optimum conditions of hemostasis with minimal tissue damage, the surgical device should rapidly elevate the temperature of the tissue to a preselected narrow range (usually between 100°C and 500°C) and should maintain the tissue temperature within that range as cutting proceeds.

Any accumulation of tissue on that portion of the surgical device that contacts tissue can interpose a thermal impedance between the device and the tissues which may inhibit heat transfer and cause the temperature of the contacted tissue to drop below the value at which the optimum conditions of hemostasis with minimal tissue damage occur. Therefore, according to the present invention, a non-adherent coating is provided on the tissue-contacting surface of the surgical device which has thermal properties and characteristics within specific limits to assure that the temperature of tissue remains within the optimum range for which hemostasis and minimal tissue damage occur.

There now follows a detailed description which is to be read with reference to the accompanying drawings of several embodiments of the present invention; it is to be clearly understood that these embodiments have been selected for description to illustrate the invention by way of example and not by way of limitation.

In the accompanying drawings:—

Figure 1 is a pictorial representation of an electrically-heated scalpel;

Figure 2 is a cross-sectional view of one embodiment of the present invention in which a heated surgical scalpel includes a non-adherent coating;

Figure 3 is a cross-sectional view of another embodiment of the present invention in which a heated surgical hemostat includes a non-adherent coating;

Figur 4 is a cross-sectional view of another embodiment of the present invention in which a sintered porous blade structure with interconnecting passages provides a reservoir of non-adherent material;

Figure 5 is a detailed cross-sectional view of an embodiment of the present invention which illustrates the non-adherent coating on the surgical instrument disposed adjacent to the tissue being cut; and

Figure 6 is a graph which illustrates the parameters of a non-adherent coating according to the present invention.

Referring now to Figure 1, there is shown a surgical scalpel having a blade protion 11 with a cutting edge 10 and an attached handle portion 8 which also carries a conductor of heating power from source 9 to the blade 11 to heat the same, as taught in the prior art. As shown in Figure 2, the surfaces of the blade 11, at least near the cutting edge 10, operate at elevated temperatures and contact tissue 13 via a non-adherent coating 12 interposed between the blade 11 and tissue 13. This eliminates the problem of tissue 13 sticking to the surfaces of blade 11 but introduces a thermal impedance between the heated blade 11 and the tissue 13 in contact therewith.

It has been determined that for portions of the blade 11 in contact with tissue, the heat flux 14 normal to or through the non-adherent coating 12 is approximately 10 to 20 times greater than the heat flux therethrough to the air for portions of the blade 11 not in contact with tissue. This produces temperature differences across the non-adherent coating 12. Thus, while the blade 11 is out of contact with tissue 13, the effective surface temperature of the non-adherent coating 12 is approximately the same as the temperature of the blade 11. However, when the blade 11 and the non-adherent coating 12 contact the tissue 13, the heat flux 14 passing through the thermal impedance presented by the non-adherent coating 12 causes the surface temperature of the non-adherent coating 12 to decrease below the desired temperature at which the optimum condition of hemostasis and minimal tissue damage occur. The temperature of the surface of the non-adherent coating 12 may be increased to the desired temperature by increasing the temperature of the blade 11 by an amount sufficient to overcome the thermal drop across the coating 12. However, because of the transient conditions associated with the blade 11 being in and out of contact with tissue 13 during a surgical procedure, the surface temperature of the coating 12 may rise excessively while out of contact with tissue to cause deterioration of the coating 12 and undesirable tissue damag upon recontact with tissue 13, as well as falling excessively when coming into contact with tissues to temperatures that are not hemostatic.

In contrast to these transient operating conditions in surgery, conventional cookware with non-adherent coatings do not involve transient opera-

tion. The heat transfer rate to an item being cooked is generally constant and is established without regard for damage to living tissue. Cookware also can be operated at higher temperatures to overcome the effects of high thermal impedance associated with thicker non-adherent coatings. However, for reasons stated above, surgical devices cannot be arbitrarily set at a temperature significantly higher than the optimum temperature at which hemostasis with minimal tissue damage occurs. Also the thicknesses of coatings typically used on cookware cannot be used on surgical devices because of the blunting effect and degradation of the cutting action of a blade that would result.

In accordance with the present invention, the non-adherent coating 12 may be formed as a solid layer or as a sacrificial solid layer or as a sacrificial liquid layer. A solid non-adherent layer 12 may be formed on the device 11 including material such as fluorocarbon polymers (exemplified by the fluorinated ethylenepropylene copolymers, polytetrafluoroethylene and polyethylene terephthalate), or silicones and polydimethylsilozanes with active end groups, for example, of hydroxyl, amine, epoxide or thiol attached to the silicone polymer via a nonhydrolyzable Si–C bond, or fluoride-metal composites such as fluoride impregnated composites, or organic phosphates. Alternatively, a sacrificial solid non-adherent coating may be formed using materials such as silicone greases or hydrocarbon, synthetic and natural ester waxes, or sulfide compounds. In addition, a sacrificial solid non-adherent coating may be formed using fluorinated ethylenepropylene copolymers which have been found to be effective in that a coating thus formed "sloughs off" in thin platelets with use to provide the desired non-adherent characteristics which respect to tissue.

With respect to Figure 4, a sacrificial liquid non-adherent coating may be provided by forming a sintered or porous blade structure 11 with substantially continuous passages therethrough which can be impregnated with a material such as silicone oil, for example, of the type based on dimethyl silicone, or ethers such as perfluoropolysynthetic fluids. The porous and impregnated structure according to Figure 4 thus establishes and maintains a continuous film of non-adherent material 12 at the surface of the device 11 which is disposed to contact tissue 13.

In accordance with the present invention, the thermal impedance of the non-adherent coating must be sufficiently low to permit transfer of heat 14 from the device 11 to the tissue 13 in contact therewith as illustrated in Figure 5. In particular, the tolerable thermal impedance of a non-adherent coating 12 depends generally upon the level of heat flux required for a particular surgical application. For example, in ophthalmic, neurological and plastic, the dermatological surgery procedures, hemostasis can be accomplished while cutting using heat fluxes well below 50 watts/cm². However, surgical procedures involving incisions in highly vascular tissues or rapid movement through tissue may require heat fluxes above 50 watts/cm² to achieve hemostasis while cutting.

As used herein, "thermal impedance" is defined as follows:

$$R = \frac{T}{(Q/A)}$$

where R refers to the thermal impedance of the non-adherent coating in units of

$$\frac{{}^\circ\mathrm{C.} \cdot \mathrm{cm}^2}{\mathrm{watt}},$$

T refers to the temperature difference across the non-adherent coating from the interface of the device 11/non-adherent coating 12 to the outer surface of the non-adherent coating 12, in units of °C, and Q/A refers to the heat flux flowing normal to or through the non-adherent coating, in units of watts/cm².

Referring to Figure 5, the maximum allowed temperature difference T across the non-adherent coating under maximum heat flux conditions should not substantially exceed about 50°C in order to optimize hemostasis while minimizing tissue damage and avoiding exposure of the surgical device and the non-adherent coating to damaging temperatures. This tolerable temperature difference thus established the thermal impedance for the heat flux levels that will be encountered during use of the surgical device. The thermal impedances, as defined above, for non-adherent coatings 12 operating at specified levels of heat flux are summarized below:

Heat Flux, Q/A (wattsicm²)	*Maximum Allowed Thermal Impedance, R, for Temperature Difference, T, of 50°C.*
10	5.0
20	2.5
30	1.7
40	1.3
50	1.0
100	0.5

These values of thermal impedance for the non-adherent coating can establish the maximum allowed thickness for various non-adherent coatings. Referring to Figure 5, the allowed thickness of the non-adherent coating 12 in a direction normal to the heat flux 14 is given by the relationship: $t = R \cdot k$ where t refers to the maximum allowed non-adherent coating thickness in units of centimeters, R is the thermal impedance, as defined previously, and k refers to effective thermal conductivity of the non-adherent coating 12 in units of watts/cm°C.

The graph of Figure 6 illustrates the relationship between maximum thickness 18 of the non-adherent coating 12 and heat flux levels corresponding to high (100 watts/cm² maximum) and low (30 watts/cm² maximum) heat flux requirements associated with various surgical procedures. By way of example, certain fluorocarbon materials that have been found effective as non-adherent coatings exhibit a thermal conductivity of about .0025 watts/cm°C. In accor-

dance with the above, the thickness of a non-adherent coating of this material should not be greater than .0013 cm (0.5 mil) for operation at high heat flux levels.

In the apparatus of Figure 3, a pinch-type instrument 15 (such as a hemostat) may be heated in conventional manner by a source of heating power connected thereto to transfer heat 14 to tissue 16 via the non-adherent coating 12 interposed therebetween. The maximum allowed thickness of non-adherent coating 12 is determined, as discussed above, with respect to the thermal impedance of the coating material and the operating level of heat flux involved.

CLAIMS

1. Surgical apparatus for non-adherently contacting tissue to heat the tissue in contact therewith to an elevated temperature at which hemostasis with minimal tissue damage occurs comprising:

heating means operable at an elevated temperature for heating the tissue; and

non-adherent coating means disposed to be intermediate the heating means and the tissue being heated thereby; said non-adherent coating means having a thermal impedance that is not substantially greater than

$$5\,\frac{°C.\cdot cm^2}{watt}.$$

2. Surgical apparatus for non-adherently contacting tissue to heat the tissue in contact therewith to an elevated temperature at which hemostasis with minimal tissue damage occurs, comprising:

heating means operable at an elevated temperatur for heating the tissue; and

non-adherent coating means disposed to be intermediate the heating means and the tissue being heated thereby; said non-adherent coating means having a thickness that is not substantially greater than .0025 cm.

3. Surgical apparatus for non-adherently contacting tissue to heat the tissue in contact therewith to an elevated temperature at which hemostasis with minimal tissue damage occurs, comprising:

heating means operable at an elevated temperature for heating the tissue; and

non-adherent coating means disposed to be intermediate the heating means and the tissue being heated thereby; said non-adherent coating means having a thermal drop thereacross while in contact with tissue that is not substantially greater than 50°C. for tissue temperatures within the range from about 100°C to about 500°C.

4. Surgical apparatus for non-adherently contacting tissue to heat the tissue in contact therewith to an elevated temperature at which hemostasis with minimal tissue damage occurs, comprising;

heating means operable at an elevated temperature for heating the tissue; and

non-adherent coating means disposed to be intermediate the heating means and the tissue being heated thereby; said non-adherent coating means having a maximum allowed thickness, t, in centimeters as given by the relationship:

$$t \leq \frac{50\cdot k}{(Q/A)}$$

where k is thermal conductivity of the non-adherent coating in watts/cm°C., and Q/A is the heat flux in watts/cm².

5. Surgical apparatus according to any of claims 1 to 4 wherein the non-adherent coating means includes a composition selected from fluorocarbon polymers and silicone polymers.

6. Surgical apparatus according to any one of claims 1 to 4 wherein the non-adherent coating means includes a composition selected from organic phosphates and metallic fluorides.

7. A method of preventing adherence of surgical apparatus to tissue at an elevated temperature at which hemostasis with minimal tissue damage occurs, the method comprising the steps of:

transferring heat to the tissue from the surgical apparatus; and

interposing between the tissue and the surgical apparatus a non-adherent coating having a thickness which is not substantially greater than .0025 cm.

8. A method of preventing adherence of surgical apparatus to tissue at an elevated temperature at which hemostasis with minimal tissue damage occurs, the method comprising the steps of:

transferring heat to the tissue from the surgical apparatus; and

interposing between the tissue and the surgical apparatus a non-adherent coating having a maximum allowed thickness, t, in centimeters as given by the relationship:

$$t \leq \frac{50\cdot k}{(Q/A)}$$

where k is thermal conductivity of the non-adherent coating in watts/cm°C., and Q/A is the heat flux in watts/cm².

9. A method of preventing adherence of surgical apparatus to tissue at an elevated temperature at which hemostasis with minimal tissue damage occurs, the method comprising the steps of:

transferring heat to the tissue from the surgical apparatus; and

interposing between the tissue and the surgical apparatus a non-adherent coating having a thermal impedance which is not substantially greater than

$$5\,\frac{°C.\cdot cm^2}{watt}.$$

10. A method of preventing adherence of surgical apparatus to tissue at an elevated temperature at which hemostasis with minimal tissue damage occurs, the method comprising the steps of:

transferring heat to the tissue from the surgical apparatus; and

interposing between the tissue and the surgical apparatus a non-adherent coating having a thermal drop thereacross while in contact with tissue that is not substantially greater than 50°C. for tissue temperatures within the range from about 100°C to about 500°C.

11. Surgical apparatus substantially as hereinbefore described with reference to the accompanying drawings.

12. A method of preventing adherence of surgical tissue at an elevated temperature at which hemostasis with minimal tissue damage occurs, substantially as hereinbefore described with reference to the accompanying drawings.

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